

# United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,577	08/20/2003	Connie Sanchez	05432/100M919-US2	5196
7278 75	90 02/07/2006		EXAMINER	
DARBY & DARBY P.C.			CHONG, YONG SOO	
P. O. BOX 5257 NEW YORK, NY 10150-5257			ART UNIT	PAPER NUMBER
			1617	
,			DATE MAILED: 02/07/200	6

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/644,577	SANCHEZ ET AL.			
Office Action Summary	Examiner	Art Unit			
	Yong S. Chong	1617			
The MAILING DATE of this communication ap	pears on the cover sheet with the o	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	OATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 12/2	<u>22/06</u> .				
· <u> </u>	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
, ====					
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 49	53 O.G. 213.			
Disposition of Claims	•				
4) ☑ Claim(s) 20-37 is/are pending in the application 4a) Of the above claim(s) is/are withdrage 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 20-37 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	awn from consideration.				
Application Papers					
9) The specification is objected to by the Examina 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	cepted or b) objected to by the drawing(s) be held in abeyance. Section is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat* See the attached detailed Office action for a list	nts have been received.  Its have been received in Applicat prity documents have been received in Applicat prity documents have been received in Application.	ion No ed in this National Stage			
Attachment(s)					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 7/11/05.</li> </ol>	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:				

Art Unit: 1617

#### **DETAILED ACTION**

### Status of the Application

This Office Action is in response to applicant's arguments filed on 12/22/2005.

Claims 20-37 are pending and are examined herein. Applicant's arguments have been fully considered. The 35 USC 103(a) rejection is withdrawn.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/984,536 because a method of treating premenstrual syndrome with escitalopram is disclosed. Although escitalopram is not disclosed to be the sole active ingredient, no other ingredients are disclosed. Therefore, it would be obvious to utilize escitalopram as the sole active ingredient.

This is a provisional obviousness-type double patenting rejection.

Art Unit: 1617

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-37 are rejected under 35 U.S.C. 103(a) as being obvious over
Boegesoe et al. (US Patent 4,943,590) and further in view of Norden et al. (US Patent 5,789,449) and the Merck Manual (16<sup>th</sup> edition, 1992, pg. 1791).

The instant claims are directed to a method of treating premenstrual syndrome by administering escitalopram.

Boegesoe et al. discloses the method of treating depression in a patient with the (+) enantiomeric form of citalopram, otherwise referred to as escitalopram (col. 1, lines 9-26), which is also disclosed to be an inhibitor of serotonin uptake. Acceptable pharmaceutical salts of escitalopram include oxalate (col. 1, lines 29-42). The daily dosage of escitalopram is disclosed to be from 5 to 50 mg (col. 8, lines 55-60).

Art Unit: 1617

However, Boegesoe et al. fail to disclose specifically a method of treating premenstrual syndrome with escitalopram.

Norden et al. teach a method of treating premenstrual syndrome by administering a serotonin reuptake inhibitor, for example citalopram, which is the racemic form of escitalopram, to a patient (col. 18, lines 36-38). Moreover, the Merck Manual teach that depression is a symptom of premenstrual syndrome (16<sup>th</sup> edition, 1992, pg. 1791).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer patients suffering from premenstrual syndrome an effective amount of escitalopram, because both premenstrual syndrome and depression are treatable by inhibiting the uptake of serotonin. Treating a patient suffering from depression with escitalopram will also treat the same patient who is suffering from premenstrual syndrome.

A person of ordinary skill in the art would have been motivated to administer escitalopram to patients suffering from premenstrual syndrome, because of the expectancy of the same amount of success when treating patients suffering from depression with escitalopram.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-5.

Application/Control Number: 10/644,577

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is

(571)-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

**YSC** 

SHENGJUNWANG 9 PRIMARY EXAMINER Page 5